

§ 159.007-11 Production inspections and tests: Yearly report.

(a) When the manufacturer uses the production inspection and test procedures in an applicable subpart he must submit a yearly report. The report is not required when inspection and test procedures approved under § 159.007-3 are used.

(b) The report must include the following:

- (1) A list of all inspections and tests performed;
- (2) A summary of the results of each group of inspections or tests;
- (3) A detailed description of any test failures; and
- (4) A statement whether or not all required tests were performed.

§ 159.007-13 Production inspections and tests: Records.

(a) The manufacturer must have a completed record with the following information for each production inspection and test:

- (1) The time, date and place of each inspection and test.
- (2) The name and title of each person performing, supervising and witnessing the inspections or tests.
- (3) The performance data for each test required in the applicable subpart, including a description of each failure.
- (4) A description or photographs of the procedures and apparatus used in the inspections or tests.

(b) The manufacturer must retain each record under this section for at least 60 months after the month in which the inspection or test was conducted.

(c) The records must be made available for examination by the Commandant upon request.

Subpart 159.010—Independent Laboratory: Acceptance, Recognition, and Termination**§ 159.010-1 Purpose.**

This subpart contains the following:

- (a) The standards and procedures under which the Coast Guard accepts an independent laboratory that a manufacturer proposes to use.
- (b) The standards and procedures under which a laboratory is accepted as

a recognized laboratory under applicable subparts.

(c) The circumstances under which the acceptance or recognition of a laboratory is terminated.

[CGD 93-055, 61 FR 13928, Mar. 28, 1996]

§ 159.010-3 Independent laboratory: Standards for acceptance.

(a) To be accepted by the Coast Guard as an independent laboratory, a laboratory must—

(1) Be engaged, as a regular part of its business, in performing inspections and tests that are the same as or similar to the inspections and tests required in the applicable subpart;

(2) Have or have access to the apparatus, facilities, personnel, and calibrated instruments that are necessary to inspect and test the equipment or material under the applicable subpart;

(3) Not be owned or controlled by—

(i) The manufacturer of the equipment or material to be inspected or tested under this subchapter or any manufacturer of similar equipment or material;

(ii) A vendor of the equipment or material to be inspected or tested under this subchapter or a vendor of similar equipment or material; or

(iii) A supplier of materials to the manufacturer;

(4) Not be dependent on Coast Guard acceptance under this subchapter to remain in business; and

(5) Not advertise or promote the manufacturer's equipment or material that the laboratory inspects and tests under this subchapter.

(b) [Reserved]

§ 159.010-5 Independent laboratory: application for acceptance.

(a) Each application for acceptance of an organization as an independent laboratory must contain the following:

(1) The name and address of the organization.

(2) A list of the equipment or material that the organization would inspect, or test, or both, under this subchapter.

(3) A description of the organization's experience and its qualifications for conducting the inspections and tests required in the applicable subpart.

(4) A description of the apparatus and facilities available to the organization for conducting those inspections and tests.

(5) If instruments are used in the required tests and inspections, a description of the instrument calibration program applying to those instruments.

(6) The position titles of personnel who are to perform, supervise, or witness those inspections or tests, along with the training and experience required for personnel in those positions.

(7) A statement signed by the chief officer of the organization or the chief officer's representative, that an official representative of the Coast Guard is allowed access upon request to the place where tests and inspections take place, to verify the information submitted in the application, or to witness tests and inspections.

(b) Each application for acceptance as an independent laboratory that is not submitted by an agency of a state or another national government, or by a classification society, must also contain the following:

(1) The name and address of each subsidiary and division of the organization, or a statement that none are involved in the testing or manufacturing of equipment approved under this subchapter.

(2) The name, title, address, and principal business activity of each of the organization's officers and directors, and the name, address, and principal business activity of each person, company, or corporation that owns at least three-percent interest in the organization or in a company or corporation that controls the organization.

[CGD 93-055, 61 FR 13928, Mar. 28, 1996]

§ 159.010-7 Recognized independent laboratory: Memorandum of Understanding.

(a) Only laboratories that have entered into an MOU with the Coast Guard may perform the functions of a recognized laboratory under this chapter.

(b) An independent laboratory seeking to become a recognized independent laboratory must submit a signed MOU to the Commandant that includes—

(1) A statement of purpose;

(2) An identification and description of the parties involved;

(3) A description of the problem resolution and appeals processes;

(4) A description of the process for measuring effectiveness and efficiency of the program under the MOU;

(5) The effective date of the MOU and terms for its termination;

(6) A statement to the effect that the MOU is not an exclusive agreement between the recognized independent laboratory and the Coast Guard;

(7) An agreement to conduct comparison testing with other recognized laboratories as directed by the Coast Guard, no more often than twice each year, with the laboratory bearing the cost of sample acquisition and testing;

(8) A statement as to how the costs of implementing the MOU will be borne; and

(9) A description of each party's responsibilities for—

(i) Equipment review and approval;

(ii) Coast Guard oversight of the recognized independent laboratory's procedures and processes;

(iii) Coordination between the parties;

(iv) Developing and maintaining regulations and standards;

(v) Handling review and approval of new and novel items not anticipated by existing regulations and standards;

(vi) Testing and inspection facilities and procedures;

(vii) Production quality control; and

(viii) Maintenance of records.

(c) The signature on the MOU required by paragraph (b) of this section must be that of the chief officer of the independent laboratory or the chief officer's representative. The Commandant or an authorized representative of the Commandant will review the MOU to ensure that it contains the information required by paragraph (b) of this section, and that the substantive provisions submitted in compliance with that paragraph are equivalent to those contained in other MOUs signed by the Commandant. If the Commandant determines that the MOU is acceptable and the independent laboratory is capable of carrying out the equipment approval functions identified in the MOU in accordance with all

appropriate requirements, the Commandant or authorized representative may at his discretion sign the MOU. Where qualitative tests or determinations are required for approval or follow-up, provision must be made for conducting comparison tests with other recognized laboratories.

(d) Copies of MOUs signed by the Commandant in accordance with this part and of lists of independent laboratories which have been accepted as recognized laboratories but which have not yet been added to the lists included in this subchapter may be obtained at the address listed in § 159.001-5.

[CGD 93-055, 61 FR 13928, Mar. 28, 1996; 61 FR 15868, Apr. 9, 1996]

§ 159.010-11 Changes in the laboratory's qualifications.

(a) If any of the information submitted under § 159.010-5(a) changes, the laboratory shall notify the Commandant in writing of each change within 30 days after the change has occurred.

(b) If any change in the independent laboratory occurs which affects its performance under the MOU required under § 159.010-7, the laboratory shall notify the Commandant in writing within 30 days after the change occurs. The Commandant may terminate the MOU, or may require amendments or revisions.

[CGD 93-055, 61 FR 13929, Mar. 28, 1996]

§ 159.010-15 Contracting inspections and tests or transferrals to another laboratory or person.

(a) No independent laboratory may contract or transfer to another person or laboratory the performance or supervision of inspections or tests, or both, required under an applicable subpart for which it is accepted or listed unless—

(1) A request in writing regarding the contract or transfer is submitted to the Commandant before the contract is executed or the transfer is completed; and

(2) The Commandant notifies the laboratory in writing that the contract or the transfer is allowed.

(b) [Reserved]

§ 159.010-17 Termination of acceptance or recognition of an independent laboratory.

The acceptance or recognition of a laboratory terminates if the laboratory—

(a) Requests termination;

(b) Is no longer in business;

(c) Knowingly fails to perform or supervise an inspection or test, or both, as required in an applicable subpart;

(d) Knowingly attests to the lack of errors, omissions, or false statement of an approval test report that contains errors omissions, or false statements;

(e) Does not meet the requirements of § 159.010-3(a);

(f) Does not comply with § 159.010-11;

(g) Contracts or transfers the performance or supervision of required inspections or tests to another laboratory or person without the approval of the Commandant; or

(h) Fails to, or in the opinion of the Commandant is unable to, carry out its responsibilities under an MOU required by § 159.010-7.

[CGD 93-055, 61 FR 13929, Mar. 28, 1996]

§ 159.010-19 Termination of acceptance or recognition: Procedure.

(a) If the Coast Guard receives evidence of grounds for termination of acceptance or recognition of an independent laboratory under § 159.010-17, the Commandant will notify the laboratory that termination is under consideration. The laboratory may submit written comments to the Commandant within 21 days of receipt of the notification. The Commandant will take all timely written comments into account before taking final action in the matter, and in no case will the Commandant take final action until at least 30 days after the laboratory has received the notification. Any final action taken by the Commandant is final agency action on the matter.

(b) If a deficiency could materially affect the validity of an approval issued under an applicable subpart, the Commandant may temporarily suspend the acceptance of the laboratory and may direct the holder of the certificate of approval to cease claiming that the

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items tested or inspected by the laboratory are Coast Guard approved, pending a final decision in the matter.

[CGD 93-055, 61 FR 13929, Mar. 28, 1996]

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